### Drug Enforcement Administration

Working to Prevent the Diversion and Abuse of OxyContin®

### □ BACKGROUND

- In recent months, concern has been growing among federal, state and local officials about the dramatic increase in the illicit availability and abuse of the prescription drug OxyContin®
- In response, the Drug Enforcement
   Administration (DEA) initiated a comprehensive effort in February 2001 to prevent the diversion of OxyContin® and reverse this trend

#### ■ BACKGROUND (continued)

OxyContin<sup>®</sup> is a controlled release form of Schedule II oxycodone



- ☐ BACKGROUND (continued)
  - Legitimately used as a medication to treat moderate to severe pain

PALIA

 Fast becoming the drug of choice for pain management with sales reaching more than \$1 billion

#### ☐ BACKGROUND (continued)

 Prescriptions dispensed for all common opioid analgesics (such as codeine, hydrocodone, morphine, and hydromorphone) during the years 1996 to 2000 increased by around

23%

 OxyContin<sup>®</sup> prescriptions dispensed during the same period increased by over

1800%

#### ☐ THE PROBLEM

 Abusers can easily compromise the controlled release formulation for a powerful morphine-like high





Photos taken of the contents of the medical bag of a physician arrested by DEA who was not only diverting but also self-abusing OxyContin<sup>®</sup>

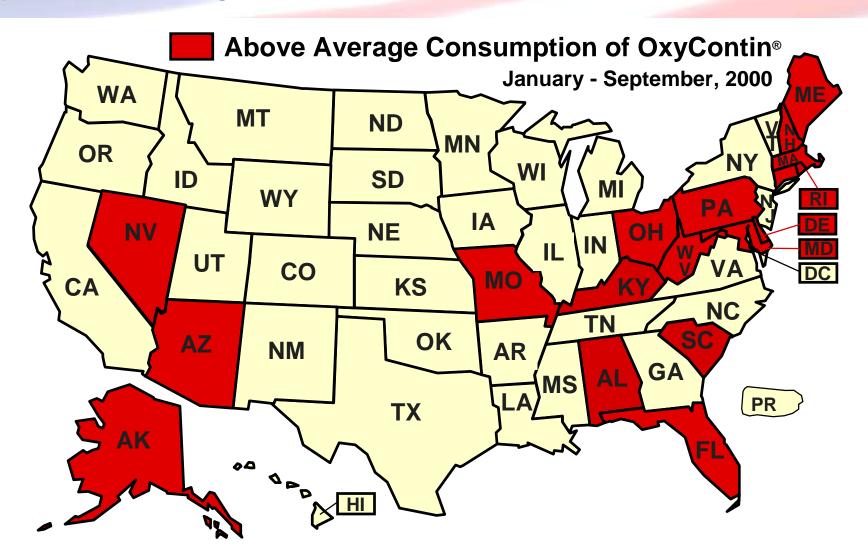
#### ☐ THE PROBLEM (continued)

- Common means of OxyContin® diversion
  - fraudulent prescriptions
  - doctor shopping
  - over-prescribing
  - pharmacy theft



- organized rings of individuals diverting and selling OxyContin<sup>®</sup>
- foreign diversion and smuggling into the U.S.

Diversion and abuse of OxyContin® appear to be concentrated in rural areas of the eastern United States but are growing problems throughout the nation



#### ☐ THE PROBLEM (continued)

- Criminal activities resulting from the abuse of OxyContin<sup>®</sup> are quickly depleting the resources, financial as well as human, of local law enforcement
  - Increasing numbers of confirmed overdose fatalities
  - As much as a 75% increase in property and other crimes related to OxyContin® addiction being reported



### DEA's GOAL

To reduce the existing and potential costs to public health and safety by having a significant and immediate impact on the criminal use and sale of OxyContin®

### ☐ Element 1: ENFORCEMENT and INTELLIGENCE

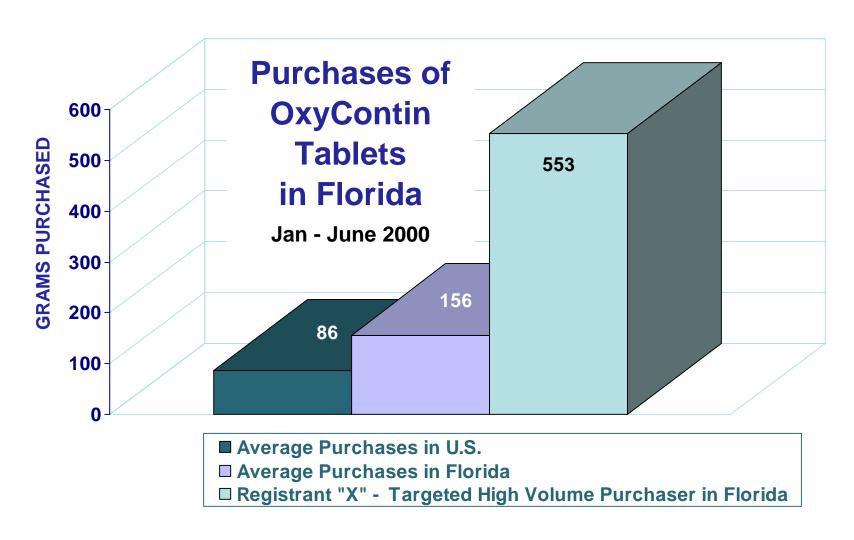
- Focus existing resources and management attention on investigations of the illicit sale and abuse of OxyContin®
- Incorporate agency and interagency efforts in both the domestic and international arenas



#### **Enforcement & Intelligence**

### **□** Examples:

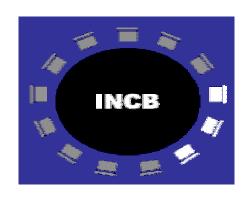
- Utilize all diversion and enforcement elements in DEA
- Participate in Healthcare Fraud Working Groups to encourage joint investigations of OxyContin® abuse
- Investigate pharmacy thefts of OxyContin® with state, local and other federal law enforcement agencies
- Utilize Tactical Diversion Squads to exchange information between DEA and the state and local agency participants
- Identify large volume purchasers of OxyContin<sup>®</sup>, such as in the following example for Florida:



#### **Enforcement & Intelligence**

- ☐ Examples: (continued)
  - Work with international organizations such as the International Narcotics
     Control Board, the World Customs
     Organization, and ICPO - Interpol







### ☐ Element 2: REGULATORY and ADMINISTRATIVE

 Utilize DEA's full range of regulatory and administrative authority to make it more difficult for abusers to obtain OxyContin®



#### **Regulatory and Administrative**

### **☐** Examples:

 Work closely with the FDA in urging the rapid reformulation of OxyContin® to reduce the abuse potential of the product



- Work with the Interagency Narcotic Treatment Review Board and the Federation of State Medical Boards on guidelines for the treatment of pain
- Ensure that the amount of the narcotic raw materials imported to make OxyContin® is sufficient only to meet legitimate medical needs

### ☐ Element 3:

### SEEK INDUSTRY COOPERATION

Voluntary compliance is the cornerstone of DEA's Diversion Control Program

### **Seek Industry Cooperation**

### **□** Examples:

- Encourage the manufacturer, Purdue Pharma, to develop a balanced marketing strategy that discusses both the dangers and benefits of OxyContin®
- Solicit support in providing educational programs alerting the legitimate user population and the general public to the dangers of abusing OxyContin®

### **Seek Industry Cooperation**

- ☐ Examples: (continued)
  - Encourage restricting OxyContin® to physicians qualified by training and experience to prescribe potent narcotics
  - Propose modifying the shape, logo, and color of dosage units to indicate the source of origin



### **Seek Industry Cooperation**

- **Examples:** (continued)
  - Work with medical organizations and international health care groups to assess the legitimate need for OxyContin®





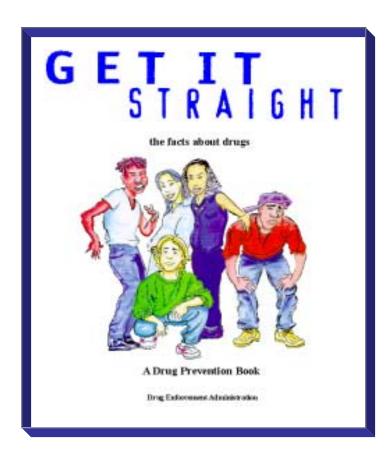


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### ☐ Element 4: OUTREACH

- Increase awareness among:
  - The Healthcare Industry
  - Other Government Agencies
  - The General Public

about the dangers associated with abuse of OxyContin®



#### **Outreach**

### ■ Examples: Healthcare Industry

 Alert the American Medical Association, Federation of State Medical Boards, National Association of Chain Drug Stores, National Association of Boards of Pharmacy, etc., to the growing problems associated with OxyContin® abuse

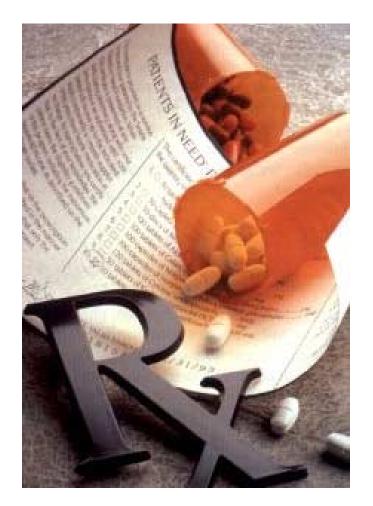




#### **Outreach**

☐ Examples: (continued)

Stress compliance with all CSA regulations concerning prescribing, dispensing, and record-keeping, the need for a proper medical relationship between doctor and patient, and the responsibility of the pharmacist



#### **Outreach**

- ☐ Examples: (continued)
  - Seek the medical community's input on ways to lessen and prevent diversion of OxyContin®



- multiple-copy prescription programs
- electronic monitoring of prescriptions
- "safe scripts"
- Meet with major private and government insurance carriers

#### **Outreach**

☐ Examples: (continued)

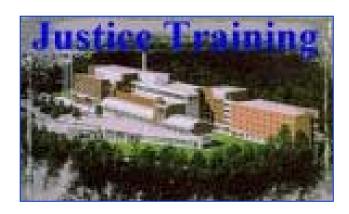
 Develop resources for use by the FDA, HHS, and the AMA in alerting practitioners to the problem





#### **Outreach**

- Examples: State and Local Government
  - Incorporate information on OxyContin® into existing DEA training programs for state and local law enforcement and regulatory agencies



Share data via newsletters & other communication methods

#### **Outreach**

- ☐ Examples: (continued)
  - Work closely with law enforcement associations such as the National Sheriffs' Association
     and the



International Association of Chiefs of Police (IACP)

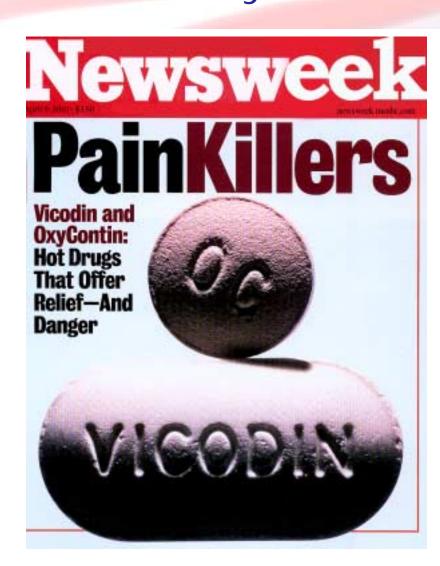
 Attend and host conferences and meetings regarding OxyContin<sup>®</sup> abuse

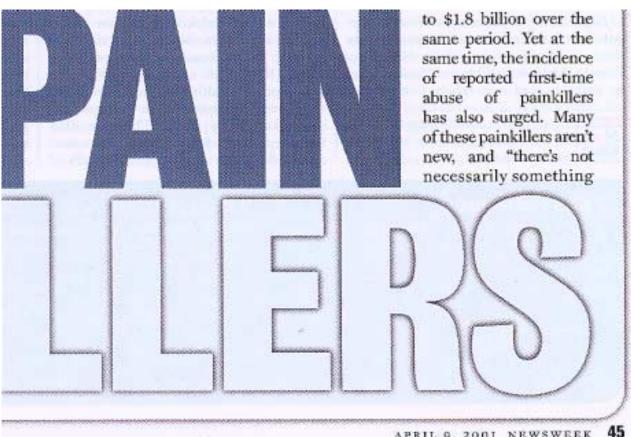


#### **Outreach**

■ Examples: General Public

 Encourage a balanced media exposure through press releases and interviews





APRIL 9, 2001 NEWSWEEK

wrong with" the increase in controlled substances, says Michael Moy in the Drug Enforcement Administration's Office of Diversion Control. "But once you put something into the food chain, someone's going to want to bite."

Although there are no perfect statistics on how many people misuse or abuse prescription drugs, in 1999 an estimated 4 million Americans over the age of 12 used prescription pain relievers, sedatives and stimulants for "nonmedical" reasons in the past month, with almost half saying they'd done so for the first time. According to the DEA, the most-abused prescription drugs include the oxycodone and hydrocodone types of painkillers, which contain potentially addictive opioids (the two drugs differ slightly in chemical structure, but both work similarly on the body).

#### **Outreach**

☐ Examples: (continued)

 Work with the ONDCP to include OxyContin® abuse in their PSAs



#### **Outreach**

- ☐ Examples: (continued)
  - Expand DEA's Demand Reduction efforts to include OxyContin® abuse
  - Utilize DEA's and
     Diversion's public internet
     web sites to include
     information on the dangers
     of OxyContin® abuse

